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| FORM PTO-1390 (Modified) REV 11-2000) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTORNEY'S DOCKET NUMBER 112701-339 |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | | | U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 10/070777 |
| INTERNATIONAL APPLICATION NO. PCT/EP00/08870 | INTERNATIONAL FILING DATE 8 September 2000 | PRIORITY DATE CLAIMED 9 September 1999 | | |
| TITLE OF INVENTION IMPROVING CONDITION OF ELDERLY PETS | | | | |
| APPLICANT(S) FOR DO/EO/US Young et al. | | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | |
| <ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c) (2)) <ol style="list-style-type: none"> <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <input type="checkbox"/> is attached hereto. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). <input checked="" type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409). <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210). | | | | |
| Items 13 to 20 below concern document(s) or information included: | | | | |
| <ol style="list-style-type: none"> <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. <input type="checkbox"/> A substitute specification. <input type="checkbox"/> A change of power of attorney and/or address letter. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). <input checked="" type="checkbox"/> Certificate of Mailing by Express Mail <input checked="" type="checkbox"/> Other items or information: | | | | |
| Return Receipt Postcard Express Mail Label No.: EL 727 382 280 US | | | | |

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| U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 10/070777 | INTERNATIONAL APPLICATION NO. PCT/EP00/08870 | ATTORNEY'S DOCKET NUMBER 112701-339 |
| 24. The following fees are submitted: | | CALCULATIONS PTO USE ONLY |
| BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : | | |
| <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1040.00 <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = | | \$890.00 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). | | <input type="checkbox"/> 20 <input type="checkbox"/> 30 \$0.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA |
| Total claims | 34 - 20 = | 14 |
| Independent claims | 12 - 3 = | 9 |
| Multiple Dependent Claims (check if applicable). | | <input type="checkbox"/> \$0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | \$1,898.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2. | | \$0.00 |
| SUBTOTAL = | | \$1,898.00 |
| Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). | | <input type="checkbox"/> 20 <input type="checkbox"/> 30 + \$0.00 |
| TOTAL NATIONAL FEE = | | \$1,898.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). | | <input type="checkbox"/> \$0.00 |
| TOTAL FEES ENCLOSED = | | \$1,898.00 |
| | | Amount to be: refunded \$ |
| | | charged \$ |
| a. <input checked="" type="checkbox"/> A check in the amount of \$1,898.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-1818 A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. | | |
| SEND ALL CORRESPONDENCE TO: | | |
| Robert M. Barrett, Esq. ATTORNEYS FOR APPLICANTS Bell, Boyd & Lloyd, LLC P.O. Box 1135 Chicago, Illinois 60690-1135 | | |
|  SIGNATURE Robert M. Barrett NAME 30,142 REGISTRATION NUMBER March 7, 2002 DATE | | |

JC10 Rec'd PCT/PTO 07 MAR 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Young et al.
Appl. No.: PCT/EP00/08870
Filed: Filed Herewith
Title: IMPROVING CONDITION OF ELDERLY PETS
Art Unit: Unknown
Examiner: Unknown
Docket No.: 112701-339

Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Sir:

Please amend the above-identified patent application as follows:

In the Claims:

Please amend Claims 3-5, 7, 10-13, 15-16, 24 and 27 as follows:

3. A method according to claim 1 in which the nutritional composition includes a zinc source.
4. A method according to claim 1 in which nutritional composition is a nutritionally complete pet food.
5. A method according to claim 1 in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.
7. A method according to claim 1 in which the nutritional composition further comprises a source of glutamine.
10. A method according to claim 8 in which the composition comprises a vitamin source providing vitamin E.

11. A method according to claim 8 in which the nutritional composition includes a zinc source.

12. A method according to claim 8 in which the nutritional composition is a nutritionally complete pet food.

13. A method according to claim 8 in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.

15. A method according to claim 8 in which the nutritional composition further comprises a source of glutamine.

16. A method according to claim 8 in which the composition is administered in an amount effective to increase the activity level of the pet.

24. A method according to claim 22 wherein the sign of aging is a decrease in activity.

27. A pet food according to claim 25 including a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

REMARKS

Pursuant to this Preliminary Amendment, Claims 3-5, 7, 10-13, 15-16, 24 and 27 have been amended.

The Preliminary Amendment does not add new matter. Moreover, Applicants note for the record, the Preliminary Amendment is not being used for purposes of narrowing the claims to avoid prior art. Rather, the Preliminary Amendment is being made to place the claims in proper U.S. format as well as remove multiple dependent claims. Therefore, Applicants do not intend to disclaim any subject matter in view of this Preliminary Amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Versions with Markings to Show Changes Made.**"

Respectfully submitted,

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BY



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 3-5, 7, 10-13, 15-16, 24 and 27 as follows:

3. (Amended) A method according to claim 1 [or claim 2] in which the nutritional composition includes a zinc source.

4. (Amended) A method according to claim 1 [or claim 2] in which nutritional composition is a nutritionally complete pet food.

5. (Amended) A method according to [any of the preceding claims] claim 1 in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.

7. (Amended) A method according to [any one of the preceding claims] claim 1 in which the nutritional composition further comprises a source of glutamine.

10. (Amended) A method according to claim 8 [or claim 9] in which the composition comprises a vitamin source providing vitamin E.

11. (Amended) A method according to [any one of claims] claim 8 [to 10] in which the nutritional composition includes a zinc source.

12. (Amended) A method according to [any one of claims] claim 8 [to 11] in which the nutritional composition is a nutritionally complete pet food.

13. (Amended) A method according to [any one of claims] claim 8 [to 12] in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.

15. (Amended) A method according to [any one of claims] claim 8 [to 14] in which the nutritional composition further comprises a source of glutamine.

16. (Amended) A method according to [any one of claims] claim 8 [to 15] in which the composition is administered in an amount effective to increase the activity level of the pet.

24. (Amended) A method according to claim 22 [or claim 23] wherein the sign of aging is a decrease in activity.

27. (Amended) A pet food according to claim 25 [or claim 26] including a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

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PCT/PCT Rec'd 07 MAR 2002

Improving Condition of Elderly PetsField of the Invention

5 This invention relates to a composition for improving the condition of elderly pets. The invention also relates to a method for improving the condition of elderly pets.

Background of the Invention

10 Elderly pets often become frail in their last few years of life. From an appearance point of view, they become thin and have poor skin and coat condition. Other symptoms include weight gain, increased water intake, digestive system problems, and joint stiffness and energy loss or lower activity levels in general. Also, the density of their bones may decrease making them susceptible to bone breakage. Further, elderly pets may be more susceptible to cancers than younger animals.

15 Certain of these problems may be effectively treated using medication. However, a better alternative would be to delay the onset of these problems, or treat these problems, through diet adjustments. In particular, elderly animals should be fed a balanced, maintenance food that contains high quality protein, lower amounts of fat to reduce energy intake, dietary fiber, and antioxidants.

20 INSERT HERE → (ANNEXURE "A") However, despite the use of balanced, maintenance foods, the condition of elderly animals may deteriorate rapidly. Therefore there is a need for nutritional ways of improving the condition and/or increasing the longevity of elderly pets.

Summary of the Invention

30 Accordingly, in one aspect, this invention provides a method for maintaining or improving the condition of elderly pets, the method comprising administering to the pet an effective amount of a nutritional composition which contains a calcium source and a source of antioxidant. The said antioxidant source may be selected from sources of vitamins and vitamin precursors. In a preferred embodiment, the source is selected from sources of vitamin E, vitamin C and β-carotene.

It is surprisingly found that the condition of elderly pets, which are administered a calcium source and a source of a nutritional agent, such as a vitamin or a vitamin precursor which has antioxidant properties, markedly improves. Further, the survivability and hence longevity of the pets improve.

5 In a further aspect, this invention provides a method for increasing the longevity of elderly pets, the method comprising administering to the pet an effective amount of a nutritional composition which contains a calcium source and a source of an antioxidant. The antioxidant source may be selected from the group of sources of vitamins and vitamin precursors.

10 Preferably, the nutritional composition includes a source of zinc. The nutritional composition may also contain a source of glutamine.

15 The invention extends further to a method of increasing the quality of life of an elderly pet, the method comprising administering to the pet a nutritional composition which contains a calcium source, a zinc source and a source of an antioxidant. The antioxidant source may be selected from β -carotene vitamin C and vitamin E.

The composition preferably is administered in an amount effective to increase the activity level of the pet.

20 According to a further aspect, the invention provides a method of increasing the activity level of an elderly pet, the method comprising administering to the pet an effective amount of a nutritional composition which contains a calcium source, a zinc source and a source of an antioxidant. The antioxidant source may be selected from, β -carotene and vitamin E.

25 The nutritional composition may also include a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. For example, the nutritional agent may be a prebiotic or a probiotic micro-organism.

Preferably, the nutritional composition is a complete and nutritionally balanced pet food.

30 In another aspect, this invention provides a pet food for elderly pets, the pet food comprising a protein source, a lipid source, a calcium source, a zinc source, β -carotene and vitamin E.

35 The pet food may comprise at least about 3 g/1000 kcal of calcium, at least about 50 mg/1000 of zinc, , at least about 5 mg/1000 kcal of β -carotene, and at least about 150 IU/1000 kcal of vitamin E.

"Prebiotic" means a substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth or development of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet at the expense of pathogenic bacteria. The result of this fermentation is a release of fatty acids, in particular short-chain fatty acids in the colon. This has the effect of reducing the pH value in the colon.

"Probiotic micro-organism" means a micro-organism which beneficially affects a host by improving its intestinal microbial balance (Fuller, R; 1989; J. Applied Bacteriology, 66: 365-378). In general, probiotic micro-organisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*.

Detailed Description of the Preferred Embodiments

Embodiments of the invention are now described by way of example only. The invention is based upon the finding that the administration to an elderly pet of an effective amount of a calcium source and a source of an antioxidant having antioxidant properties, improves the condition and/or longevity of the pet. By "elderly" is meant a pet of age 7 years or more, although in certain cases, younger pets may exhibit characteristics and conditions generally associated with older animals. In preferred embodiments, the source of antioxidant is a source of vitamins or vitamin precursors.

The calcium source and the source of vitamins which have antioxidant properties, are administered as part of a nutritional composition. The nutritional composition is conveniently formulated into a pet food. The pet food may be any suitable pet food, for example a canned pet food, a semi-moist pet food, or a dried pet food. Further, the exact composition of the pet food is not critical.

The pet food thus contains a source of antioxidants, advantageously selected from the group of sources of vitamins and vitamin precursors. Suitable examples of such antioxidants include β -carotene, vitamin E and vitamin C. Preferably the pet food contains β -carotene and vitamin E.

If β -carotene is used, it may be present in an amount above about 4 mg/1000 kcal. For example, the nutritional composition may contain about 5 mg/1000 kcal of β -carotene. The vitamin E may be present in an amount of above about 75 IU/1000 kcal; for example above about 150 IU/1000 kcal.

5

The pet food contains a calcium source. Suitable calcium sources include calcium carbonate, calcium phosphate (di or tribasic), calcium chloride, calcium citrate bone meal (or bones, for example, chicken necks & backs), or other bioavailable sources of calcium. The pet food preferably contains about 1.5 g/1000 kcal to about 6 g/1000 kcal of calcium; for example about 4.5 g/1000 kcal.

10

The pet food may also contain vitamin D, vitamin K and zinc. The vitamin D may be present in an amount of about 500IU/1000kcal to about 190000IU/1000kcal. The vitamin K may be present in an amount of above about 0.07mg/1000kcal; for example about 0.125mg/1000kcal. Other minerals and vitamins may also be included.

15

The pet food preferably contains a source of zinc. Zinc may be provided, by way of example, in the form of zinc sulfate, zinc oxide and zinc-methionine. Further, many ingredients commonly used in pet foods are sources of zinc. The pet food preferably contains about 50 mg/1000 kcal to 500 mg/1000 kcal of zinc.

20

The pet food may contain a protein source. Any suitable protein source may be used. Suitable protein sources may be selected from any suitable animal or vegetable protein source; for example muscular or skeletal meat, meat and bone meal, poultry meal, fish meal, milk proteins, corn gluten, wheat gluten, soy flour, soy protein concentrates, soy protein isolates, egg proteins, whey, casein, gluten, and the like. For elderly animals, it is preferred for the protein source to contain a high quality animal protein.

25

The amount of protein provided by the protein source may be selected as desired. For example, the pet food may contain about 12% to about 70% by weight of protein on a dry basis.

30

The pet food may contain a carbohydrate source. Any suitable carbohydrate source may be used. Preferably the carbohydrate source is provided in the form of grains, flours and starches. For example, the carbohydrate source may be rice, barley, sorghum, millet, oat, corn meal or wheat flour. Simple sugars such as sucrose, glucose and corn syrups may also be used.

The amount of carbohydrate provided by the carbohydrate source may be selected as desired. For example, the pet food may contain up to about 60% by weight of carbohydrate.

35

The pet food may contain a fat source. Any suitable fat source may be used; both animal fats and vegetable fats. Preferably the fat source is an animal

fat source such as tallow. Vegetable oils such as corn oil, sunflower oil, safflower oil, rape seed oil and the like, may also be used. If desired, the fat source may include long chain fatty acids. Suitable long chain fatty acids include alpha-linoleic acid, gamma linolenic acid, linoleic acid, eicosapentanoic acid, and docosahexanoic acid. Fish oils are a suitable source of eicosapentanoic acids and docosahexanoic acid. Borage oil, blackcurrent seed oil and evening primrose oil are suitable sources of gamma linolenic acid. Safflower oils, sunflower oils, corn oils and soy bean oils are suitable sources of linoleic acid.

The amount of fat provided by the fat source may be selected as desired. For example, the pet food may contain about 5% to about 50% by weight of fat on a dry basis. Preferably, the pet food has a relatively reduced amount of fat.

The exact composition of the protein source, the carbohydrate source and the fat source is not critical and will be selected based upon palatability, availability, cost and processing considerations.

The pet food may also include additional ingredients such as salts, spices, seasonings, flavoring agents, gums, prebiotics and probiotic micro-organisms. Suitable prebiotics include oligosaccharides, such as inulin and its hydrolysis products commonly known as fructooligosaccharides, galacto-oligosaccharides, xylo-oligosaccharides or oligo derivatives of starch.

The prebiotics may be provided in any suitable form. For example, the prebiotic may be provided in the form of plant material which contains the prebiotic. Suitable plant materials includes asparagus, artichokes, onions, wheat or chicory, or residues of these plant materials. Alternatively, the prebiotic may be provided as an inulin extract or a hydrolyzed inulin extract. Extracts from chicory are particularly suitable. Suitable inulin extracts are commercially available.

The probiotic micro-organism may be selected from one or more micro-organisms suitable for animal consumption and which is able to improve the microbial balance in the intestine.

Examples of suitable probiotic micro-organisms include yeasts such as *Saccharomyces*, *Debaromyces*, *Candida*, *Pichia* and *Torulopsis*, moulds such as *Aspergillus*, *Rhizopus*, *Mucor*, and *Penicillium* and *Torulopsis* and bacteria such as the genera *Bifidobacterium*, *Bacteroides*, *Fusobacterium*, *Melissococcus*, *Propionibacterium*, *Streptococcus*, *Enterococcus*, *Lactococcus*, *Staphylococcus*, *Peptostreptococcus*, *Bacillus*, *Pediococcus*, *Micrococcus*, *Leuconostoc*, *Weissella*, *Aerococcus*, *Oenococcus* and *Lactobacillus*. Specific examples of suitable

probiotic micro-organisms are: *Saccharomyces cereviseae*, *Bacillus coagulans*, *Bacillus licheniformis*, *Bacillus subtilis*, *Bifidobacterium bifidum*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Enterococcus faecium*, *Enterococcus faecalis*, *Lactobacillus acidophilus*, *Lactobacillus alimentarius*,
5 *Lactobacillus casei* subsp. *casei*, *Lactobacillus casei Shirota*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii* subsp. *lactis*, *Lactobacillus farciminus*, *Lactobacillus gasseri*, *Lactobacillus helveticus*, *Lactobacillus johnsonii*,
10 *Lactobacillus reuteri*, *Lactobacillus rhamnosus* (*Lactobacillus GG*), *Lactobacillus sake*, *Lactococcus lactis*, *Micrococcus varians*, *Pediococcus acidilactici*, *Pediococcus pentosaceus*, *Pediococcus acidilactici*, *Pediococcus halophilus*, *Streptococcus faecalis*, *Streptococcus thermophilus*, *Staphylococcus carnosus*, and *Staphylococcus xylosus*. The probiotic micro-organisms may be in powdered, dried form; especially in spore form for micro-organisms which form spores. Further, if desired, the probiotic micro-organism may be encapsulated to
15 further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix. Alternatively, the micro-organism may be applied to a body or particle of pet food such as a kibble in a coating mixture. Such mixture may comprise a lipid-based carrier and suitable preserving or protective agents for the micro-organism. Further alternatively, it may be provided as a separately contained supplement to the main food composition,
20 such as for example in a sachet provided with the composition in its packaged form, preferably at point of sale.

The pet food may also include a glutamine source. Suitable sources of glutamine include glutamine in free amino acid form, glutamine in di-peptide form and proteins obtained sorghum, millet, oat, and carob. Gluten also provides a suitable source of glutamine.
25

The pet food may be produced using any suitable process. Suitable processes for wet products include the following:-

Process (i): To produce a thermally gelled emulsion which sets upon cooling, a suitable meat material is comminuted to produce a meat batter. Suitable gelling agents, for example starches and gums such as kappa-carrageenan, locust bean gum, guar gum, and xanthan gum may be added to the meat batter. Usually no more than about 1% by weight of gum is needed.
30

Water may also be added the meat batter to provide from about 70% to about 85% by weight of moisture. If sufficient moisture is present in the meat material, water need not be added.
35

The meat batter is then heated to a temperature suitable to initiate thermal gelling of the mixture; for example a temperature of about 40°C to about 65°C in a mixer-cooker. Steam may be injected into the meat batter if desired. The heated meat batter may be emulsified if desired. The meat batter is then maintained at a temperature of about 40°C to about 65°C until needed. After retorting and cooling to room temperature, the meat batter forms a thermally gelled emulsion which is substantially solid or at least holds its form.

Process (ii): To produce solid food pieces in gravy or gel, solid pieces of meat or other material, or both, may be mixed with a gravy. Solid pieces of other materials may also be used; such as rice grains, pasta or noodles, vegetable pieces, and the like.

The solid food pieces may be in the form of pieces of a thermally gelled matrix. The pieces of the thermally gelled matrix may be produced by any suitable procedure, for example the procedures described in any one of US patents 4,781,939, 5,132,137 and 5,567,466 and PCT application WO 97/02760.

The thermally gelled matrix may be formed in suitable equipment such as an emulsion mill or an extruder to form pieces or chunks. If an extruder is used, the emulsion may be forced through an orifice to provide the emulsion with a desired shape; for example of oval, square or rectangular cross-section. The extrudate may then be cooked in a suitable continuous cooking system; for example a tunnel oven using hot air, steam, mixtures of hot air and steam, or microwaves as the heating medium. The core temperature of the extrudate is raised such that the extrudate undergoes thermal gelling. For example, the core temperature may be raised to at least about 80°C; for example about 85°C to about 95°C. The gelled extrudate may then be cut into pieces and the pieces cooled to provide pieces of a thermally gelled matrix. The pieces may be subjected to flaking if desired. The cooling may be carried out by spraying water on the pieces. Alternatively, other cooling media may be used.

If a gravy is used with the solid food pieces, it may be produced from water, one or more starch or gums, and suitable flavoring agents. The gravy preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and gravy. Suitable gums are kappa-carrageenan, locust bean gum, guar gum and xanthan gum.

If a gel is used with the solid food pieces, it may be produced from a suitable gelling agent, water and suitable flavoring agents. The gel preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and

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gravy. Suitable gelling agents are proteins such as gelatin; gums such as alginates, kappa-carrageenan, locust bean gum, guar gum and xanthan gum, and the like. The gel or aspic may be prepared as is conventional.

Products which use a combinations of the processes described above may 5 also be used. For example, a thermally gelled emulsion may be prepared as described above. Then solid food pieces, which may be pieces of a thermally gelled matrix, meat pieces, vegetable pieces, combinations of these pieces, and the like, are combined with the thermally gelled emulsion. As a further alternative, combinations of thermally gelled emulsions and solid food pieces in 10 gravy or gel, may be used. Suitable combinations are described in WO 98/05218 and WO 98/05219; the disclosures of which are incorporated by reference.

The pet foods are then filled into cans or other containers, the containers sealed, and the products retorted in the normal manner. Suitable equipment is commercially available.

15 A suitable process for a dried pet food is cooking a feed mixture of the various ingredients, forming the cooked mixture into pellets, drying, and then coating the pellets with flavors. The cooking and forming steps are preferably carried out using an extruder, as is well known in the art. However, the pellets may be produced by other cooking procedures such as baking a preformed food body comprising the selected ingredients, preferably in nutritionally balanced 20 proportions.

25 The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon the size of the pet, the type of pet and the age of the pet. However an amount of the nutritional composition to provide a daily amount of at least about 0.2^mg/kg body weight of β-carotene, at least about 3 IU/kg body weight of vitamin E, and at least about 0.12 g/kg body weight of calcium, would usually be adequate. Preferably at least about 2 mg/kg body weight of zinc is administered. For example, for a cat weighing about 4 kg, a daily amount of at least about 0.25^mg/kg body weight of β-carotene, at least about 3.5 IU/kg body 30 weight of vitamin E, at least about 0.15 g/kg body weight of calcium and at least about 2.5 mg/kg body weight of zinc, may be fed. For example, for a dog weighing about 20 kg, a daily amount of at least about 0.2^mg/kg body weight of β-carotene, at least about 3 IU/kg body weight of vitamin E, at least about 0.12g/kg body weight of calcium and at least about 2mg/kg body weight of zinc, may be 35 fed.

It is believed that by providing a pet food composition as provided for above, making it available to minders or owners of elderly pets and drawing attention to the prospect that regular feeding of the composition to such pets can bring about at least a temporary reversal of at least some of the signs of aging in
5 their pet, the pet minder will be encouraged to administer the pet the composition on a regular basis. A suitable way of drawing the attention of the minder to the benefits of the composition would be by way of notice on the packaging of the food composition, alternatively by separate advertising thereof.

Numerous modifications may be made to the embodiments described above
10 without departing from the scope of the invention. Specific examples are now described for further illustration.

Example 1

Thirty six cats are used in a trial. The cats are at least 10 years of age and
15 are in a frail or borderline frail condition. Both male and female cats are used and the numbers are roughly equal across treatments. The cats are screened for hyperthyroidism.

The cats are separated into 4 groups of 9 cats each. Each group has roughly the same amount of hyperthyroid cats as any other group. Also, the male:female
20 ratio for each group is roughly the same.

Each cat is housed in a cage and is subjected to a light cycle of 12 hours darkness and 12 hours light. The temperature is ambient. The cages are cleaned daily. Each cat has *ad libitum* access to food and water except prior to the taking of any blood sample when the cats are fasted overnight.

All cats are fed a canned control diet for a pre-test period of 7 weeks. A blood sample is taken and blood superoxide dismutase levels, calcium, Complete Blood Count (hemoglobin, hematocrit, red blood cell number), albumin and protein are determined.
25

Each group of cats is then fed a different diet for a period of 6 months. The diets are as follows:
30

Control Diet:- A canned pet food which is highly palatable to cats. The food contains 24.7% added water, about 73.7% meat, about 1% starch and flavors, minerals and vitamins; all by weight. The food contains normal levels of vitamins and minerals.

Diet A:- The control diet but containing an additional 5 mg/1000kcal of β -carotene and 100 IU/1000 kcal of vitamin E;
35

Diet B:- The control diet but containing an additional 3 g/100kcal calcium, 1500 IU/1000kcal vitamin D, 0.05 mg/1000kcal vitamin K and 40 mg/1000kcal zinc.

5 Diet C:- The control diet but containing and additional 5 mg/1000 kcal of β-carotene, 100 IU/1000 kcal of vitamin E, 3 g/100 kcal calcium, 1500 IU/1000 kcal vitamin D, 0.05 mg/1000 kcal vitamin K and 40 mg/1000 zinc.

The cats are examined upon commencement of the trial, after 3 months and after 6 months. The examination includes:

10

- a physical examination;
- a subjective assessment of body condition;
- determination of blood superoxide dismutase levels, calcium balance, Complete Blood Count (hemoglobin, hematocrit, red blood cell number), albumin and protein.

The results are as follows:-

| Change in: | Control Diet | Diet A | Diet B | Diet C |
|-----------------------------|--------------|--------|--------|--------|
| Surviving cats | 75% | 75% | 55% | 100% |
| Hematocrit (%) | 1.5 | 3.6 | -0.4 | 3.6 |
| Red Blood cell (m/cu mm) | 0.101 | 0.976 | -0.23 | 0.621 |
| Total protein | -0.6 | -0.3 | -0.8 | 0.3 |

20

All cats fed Diet C have improved longevity. The cats fed diets A and C have a significant improvement in hematocrit, hemoglobin, and red blood cell levels. Indeed, these represent at least a partial reversal to levels associated with far younger cats. While total blood protein decreases in cats fed the control diet, it does not decrease in cats fed diets A and C. Decreased hemoglobin, hematocrit, red blood cell number, and protein are commonly observed in elderly pets. Diet B, which contains calcium but not the antioxidant vitamins A and E, performs worse than the control. Hence combining calcium with the antioxidant vitamins A and E offers a surprising and synergistic improvement.

25

Example 2

30

The effect of the diet of the present invention was monitored over a period of six months in a group of thirty six elderly cats. Each cat was over 8 years of age at commencement of the trial. The cats were divided into two groups

5

(Control and Diet A) of 18 cats each having similar age profiles. The cats are screened prior to being chosen for the trial to eliminate those with known pre-existing disease conditions. Preliminary screening is performed by: physical examination, cbc, serum chemistries, thyroid hormone and urinalysis including urine protein/creatinine ratio. These parameters are all routinely recommended in the veterinary evaluation of geriatric pets.. In each group, cats are blocked for assignment to diets on the basis of sex, age, and a "health status" parameter to be derived from initial screening tests listed above

10 Each cat is housed in a cage and is subjected to a light cycle of 12 hours darkness and 12 hours light. The temperature is ambient. The cages are cleaned daily. Each cat has *ad libitum* access to food and water. For a month prior to commencement of the trial, both groups are fed a standard diet, available commercially under the brand name Friskies Salmon.

15 From the commencement date, Control continued to be fed the Friskies Salmon diet as a control, while Diet A was fed a diet consisting of Friskies Salmon plus the following additives: 5 mg/1000kcal of β -carotene and 100 IU/1000 kcal of vitamin E. Calcium content was approximately 4.5 g/1000 kcal ME.

20 Each participating cat wears a collar having an activity monitor that contains an accelerometer mounted thereon. The activity monitor was a model Actiwatch 16 manufactured by Mini Mitter Co. , Inc., (Sunriver, Oregon, USA). The activity monitor is capable of sensing any motion and integrates degree and intensity of motion. The monitor provides the data tabulated below:

25

Table 1

| Diet | Average Activity per 24 hours | | | |
|----------------|--------------------------------------|-----------------|----------------------------|--------------------------------|
| | 0 months | 6 months | Change from Initial | % of Cats With Increase |
| Control | 112'603 | 59'958 | -52'644 | 0.0 |
| Diet A | 65'056 | 84'205 | 19'148 | 100.0 |

Table 2

| <u>Diet</u> | Number of Minutes Active per Day | | | |
|----------------|---|-----------------|----------------------------|--------------------------------|
| | <u>0 months</u> | <u>6 months</u> | <u>Change from Initial</u> | <u>% of Cats With Increase</u> |
| Control | 90.4 | 40.1 | -50.3 | 0.0 |
| Diet A | 52 | 61.8 | 9.8 | 100.0 |

Table 3

| <u>Diet</u> | Number of Minutes Alert or Active per Day | | | |
|----------------|--|-----------------|----------------------------|--------------------------------|
| | <u>0 months</u> | <u>6 months</u> | <u>Change from Initial</u> | <u>% of Cats With Increase</u> |
| Control | 370.9 | 235.7 | -135.2 | 0.0 |
| Diet A | 252.2 | 298.3 | 46 | 100.0 |

5

Table 4

| <u>Diet</u> | Number of Hours Alert or Active per Day | | | |
|----------------|--|-----------------|----------------------------|--------------------------------|
| | <u>0 months</u> | <u>6 months</u> | <u>Change from Initial</u> | <u>% of Cats With Increase</u> |
| Control | 6.18 | 3.93 | -2.25 | 0.0 |
| Diet A | 4.20 | 4.97 | 0.77 | 100.0 |

Table 5

| <u>Diet</u> | Average Activity per Alert or Active Period (Activity Score/Min) | | | |
|----------------|---|-----------------|----------------------------|--------------------------------|
| | <u>0 months</u> | <u>6 months</u> | <u>Change from Initial</u> | <u>% of Cats With Increase</u> |
| Control | 299.4 | 255.6 | -43.9 | 0.0 |
| Diet A | 227.5 | 256.5 | 29.0 | 66.7 |

10

The cats in the control diet group (Control) experience a decline in activity. This decline is in line with expectations for a 6 month period at their age. In contrast, elderly cats fed on the antioxidant-containing diet of Diet A demonstrate remarkable increases in activity levels. This provides evidence of an increase in ease of movement and therefore of a general improvement in quality of life.

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Claims

1. A method for improving the condition of elderly pets, the method comprising administering to the pet an effective amount of a nutritional composition which contains a calcium source and a source of an antioxidant, being a vitamin precursor.
2. A method according to claim 1 in which the precursor is β -carotene.
3. A method according to claim 1 or claim 2 in which the nutritional composition includes a zinc source.
4. A method according to any one of the preceding claims in which the nutritional composition is a nutritionally complete pet food.
5. A method according to any one of the preceding claims in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.
6. A method according to claim 5 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
7. A method according to any one of the preceding claims in which the nutritional composition further comprises a source of glutamine.
8. A method for increasing the longevity or quality of life of an elderly pet, the method comprising administering to the pet an effective amount of a nutritional composition which contains a calcium source and a source of an antioxidant, being a vitamin precursor.
9. A method according to claim 8 in which the precursor is β -carotene.
10. A method according to claim 8 or claim 9 in which the composition comprises a vitamin source providing vitamin E.

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11. A method according to any one of claims 8 to 10 in which the nutritional composition includes a zinc source.

5 12. A method according to any one of claims 8 to 11 in which the nutritional composition is a nutritionally complete pet food.

10 13. A method according to claim any one of claims 8 to 12 in which the nutritional composition further comprises a prebiotic and/or a probiotic micro-organism.

14. A method according to claim 13 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.

15 15. A method according to any one of claims 8 to 14 in which the nutritional composition further comprises a source of glutamine.

20 16. A method according to any one of claims 8 to 15 in which the composition is administered in an amount effective to increase the activity level of the pet.

25 17. A method for increasing the longevity of an elderly cat, the method comprising administering to the cat an effective amount of a nutritional composition which contains a calcium source, a zinc source, β -carotene, and vitamin E.

30 18. A method according to claim 23 in which the elderly cat is administered a daily amount of at least about 0.25 mg/kg body weight of β -carotene, at least about 3.5 IU/kg body weight of vitamin E, at least about 0.15 g/kg body weight of calcium and at least about 2.5 mg/kg body weight of zinc.

35 19. A method of increasing the activity level of an elderly cat, the method comprising administering to the cat an effective amount of a nutritional composition which contains a calcium source, a zinc source, β -carotene and vitamin E.

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20. A method for increasing the longevity of an elderly dog, the method comprising administering to the dog an effective amount of a nutritional composition which contains a calcium source, a zinc source, β -carotene and vitamin E.

5

21. A method according to claim 20 in which the elderly dog is administered a daily amount of at least about 0.2 mg/kg body weight of β -carotene, at least about 3 IU/kg body weight of vitamin E, at least about 0.12 g/kg body weight of calcium and at least about 2 mg/kg body weight of zinc.

10

22. A method for reversing a sign of aging in an elderly pet comprising administering to the pet a nutritional composition comprising a source of calcium and a source of an antioxidant.

15

23. A method according to claim 22 wherein the antioxidant source is selected from sources of vitamins and vitamin precursors.

24. A method according to claim 22 or claim 23 wherein the sign of aging is a decrease in activity.

20

25. A pet food for elderly pets, the pet food comprising a protein source, a lipid source, a calcium source, a zinc source, β -carotene and vitamin E.

25

26. A pet food according to claim 25 which comprises at least about 3 g/1000 kcal of calcium, at least about 50 mg/1000 kcal of zinc, at least about 5 mg/1000 kcal of β -carotene, and at least about 150 IU/1000 kcal of vitamin E.

30

27. A pet food according to claim 25 or claim 26 including a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

35

28. A pet food according to claim 27 in which the nutritional agent is selected from the group comprising prebiotics and probiotic micro-organisms.

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29. A process for reversing a sign of aging in an elderly pet comprising the steps of providing a pet food composition comprising a source of calcium and a source of an antioxidant, making the composition available to a minder of an elderly pet and providing means of encouraging the pet minder to administer the said composition to the pet on a regular basis.

5

30. A process for maintaining or increasing total blood protein in an elderly pet comprises administering to the pet a foodstuff comprising a source of calcium and a source of an antioxidant.

10

31. A process according to claim 30 wherein the foodstuff is capable of providing the pet a daily amount of at least about 0.25 mg/kg of the pet's body weight of β -carotene, at least about 3.5 IU/kg body weight of vitamin E, at least about 0.15 g/kg body weight of calcium and at least about 2.5 mg/kg body weight of zinc.

15

32. Use of a petfood composition for the increasing of total blood protein in an elderly pet, the composition having been formulated to provide at least about 0.25 mg/kg of the pet's body weight of β -carotene, at least about 3.5 IU/kg body weight of vitamin E, at least about 0.15 g/kg body weight of calcium and at least about 2.5 mg/kg body weight of zinc when fed as a complete meal.

20

33. Use of a petfood composition to increase physical energy levels in an elderly pet, the composition comprising an effective amount of a nutritional composition which contains a calcium source, a zinc source, β -carotene and vitamin E.

25

34. Use of a nutritional composition in reversing a sign of aging in an elderly pet, the composition comprising a source of calcium, zinc and a source of an antioxidant.

30

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(54) Title: IMPROVING CONDITION OF ELDERLY PETS

(57) Abstract: A method is provided for improving the condition and/or increasing the longevity of elderly pets. The elderly pet is administered an effective amount of a nutritional composition which contains a calcium source and an antioxidant source, such as of vitamins or vitamin precursors which have antioxidant properties. Examples of such vitamins and precursors include β-carotene and vitamin E.

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

IMPROVING CONDITION OF ELDERLY PETS

the specification of which: (check one)

is attached hereto.

was filed on 8 September 2000, as United States Application No. or PCT International Application No. PCT/EP00/08870 and was amended on 7 March 2002 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent Office all information which is known to me to be material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

| Number | Country | Day/Month/Year Filed | Priority Not Claimed |
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I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

Application Serial No.

60/152,984

Filing Date

September 9, 1999

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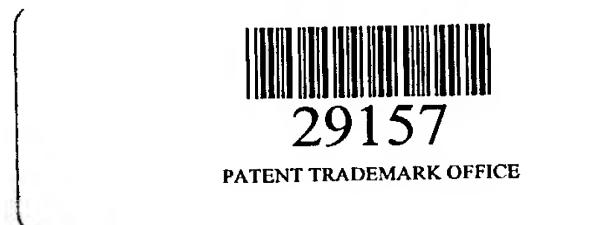
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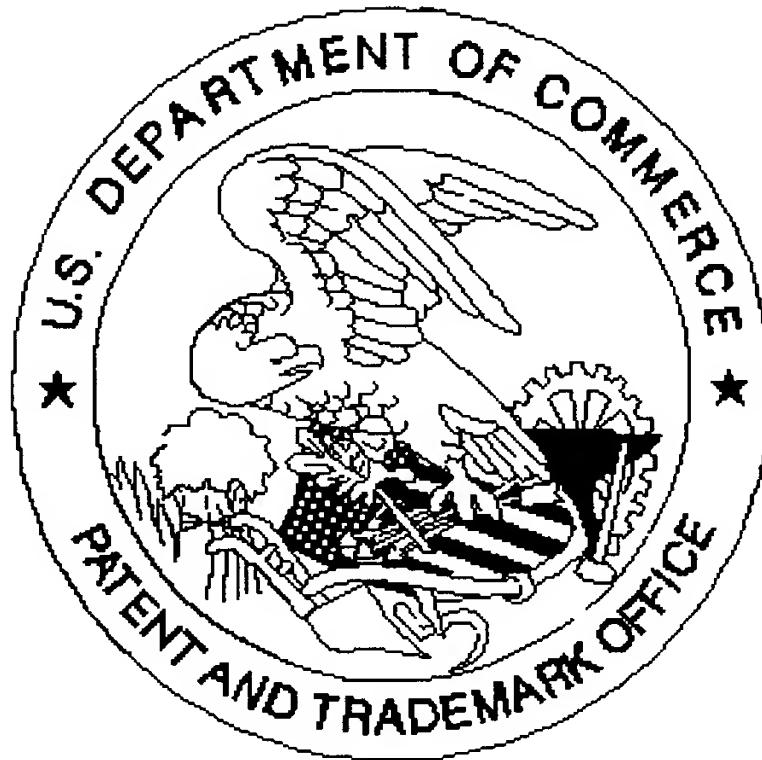
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